

8. STATEMENT OF SAFETY AND EFFECTIVENESS

The sponsor, Technical Chemicals and Products, Inc. (3340 S.W. 15th Street, Pompano Beach, Florida, 33069), has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Methamphetamine and its metabolites in a screening format. This summary was originally written in May of 1995 and has been updated as of January, 1997.

The trade name of the device is One Step™ Urine Drug of Abuse Methamphetamine Test having a designated common name of Methamphetamine Test System and a classification as a class II device per 21 CFR ¶ 862.3610. This device is intended for professional medical/forensic screening of urine for Methamphetamine.

TCPI's One Step™ Urine Drug of Abuse Methamphetamine Test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody:antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 500 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

Initial testing of the TCPI One Step Methamphetamine Test yielded a relative sensitivity and specificity of 1.00 and a concordance of 100% when tested against Sigma SIA™ on samples documented to be positive by GC/MS. A clinical trial consisting of 300 samples was run and the data yielded agreement within the positive samples of 1.00, and agreement within the negative samples of 0.907 when compared to GC/MS and an accuracy of 94.67%. When all the data was combined, the agreement within the positive samples remained 1.00, while the agreement within the negative samples rose to 0.948 with a concordance of 97.24%. Like all of the screening methods tested TCPI's will report false positives when ephedrine and phenyl propanolamine are present.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, Exec Vice President, Technical Chemicals & Products, Inc. at 805-522-6223(Ca) or by fax at 805-522-1526.

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